



Lloyd's Register Technical Association

AN INTRODUCTION TO EC DIRECTIVES AND THEIR APPLICATION

by

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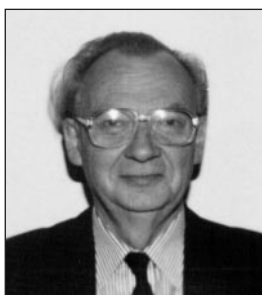
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G. G. Ferrier and M. Hayter



George Ferrier entered the Merchant Navy as an Engineer Cadet with B.I.S.N. Co. immediately after leaving school. He progressed on to become 2nd Engineer Officer, obtained a Combined First Class Certificate and left in 1972 to study for the Extra First Class Certificate. This was followed by a period of teaching Engineering and Control subjects at Glasgow College of Nautical Studies prior to joining Lloyd's Register (LR) in 1975. His initial appointment was in the Control Engineering Department followed by a period as Owner's Representative at shipyards in Belfast and Yugoslavia. He continued on with classification work for a further two years before transferring to the Orient. The next 10 years were spent in Korea and China at various locations covering all aspects of LR's work in the shipping, offshore and industrial sectors. He was Senior Surveyor responsible for all LR's Industrial work in Korea when he returned to the UK in December 1991 to take up his present position in the Type Approval Department. He is currently serving as Principal Surveyor for the Type Approval Department which covers responsibility for the operation of LR's Type Approval System and the recently developed Product Certification System for EC Directives. This responsibility includes the monitoring of EC Directives, obtaining Notified Body status and developing LR's role in this field.



Mike Hayter graduated in 1954 with a Degree in Mechanical Engineering from Bristol University. He served as an Engineering Officer in the Royal Air Force during the period 1954-56. He went on to work as a technical officer in the Experimental Department of the Hawker Aircraft Company for two years before moving on to Atomic Power Constructions Limited. He was accepted as a full Member of the Institution of Mechanical Engineers in 1964 and was subsequently designated Chartered Engineer. He worked for three years in the petrochemical industry before returning to the power industry to work for the Central Electricity Generating Board. In 1970, he joined the Department of Trade and Industry where he was involved with negotiating the UK's industrial position in the European Economic Community. This work continued until 1977 when he took charge of a section sponsoring UK manufacturers of food, drink and packaging machinery. In 1981 he returned to EC work when he became lead negotiator of Community Directives for the removal of barriers to trade in the engineering sector. His task was to formulate the UK policy line, and then to negotiate in Brussels on behalf of the UK. He joined LR in 1994 and is currently working as a consultant in the Type Approval Department.

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SYNOPSIS

This paper is set out in three main sections, and aims to introduce EC Directives along with their application, giving a general understanding of the Single European Market, a few of the Directives and a typical EC Type Examination procedure.

The introductory section covers the Single Market and how it is achieved through the development and use of Directives. It explains the structure of Directives and in particular details the various paths of attestation which may be called up in individual Directives, which allow manufacturers to demonstrate compliance with the Directive. Finally it explains the use and purposes of the CE marking.

The second section summarises a selection of the following Directives which are of interest to Lloyd's Register; Simple Pressure Vessels, Machinery Directive, Recreational Craft Directive, Personal Protective Equipment Directive, Electromagnetic Compatibility Directive and Low Voltage Directive.

Section three deals with a typical EC Type Examination procedure based on the Machinery Directive.

The paper is not intended to be exhaustive on the subject and should further information be required, the individual Directives must be consulted.

1. INTRODUCTION

1.1 The Single Market

In 1957 when the original Treaty of Rome (the Treaty) was signed it had as one of its main aims the creation of what subsequently became known as the Four Freedoms. These were the freedom of movement of:

- People
- Finance
- Services
- Goods

The Argument was that, if these four aspects of commercial life could move freely between the signing Member States, a Common, or Single Market would have been achieved. However, it was clearly realised that such freedom did not already exist because the controlling laws of individual Member States differed from each other in their specific requirements. Hence compliance with the laws of one Member State was not recognised as giving compliance with those of other Member States.

In order to overcome this situation – the situation that became known as technical barriers to trade – The Treaty set up a mechanism by which the laws of Member States could be harmonised. This mechanism was embodied in Article 100 of the Treaty and comprised a procedure by which the Member States would agree the text of common laws pertaining to particular aspects of trade. These texts would be embodied in documents called Directives, by which Member States agreed to align their laws to the common text and by a given date.

Since 1957 there have been two major modifications to the Treaty in both of which there has been a streamlining of the procedure for formulating and agreeing Directives. In particular, a framework structure has been set up that all Directives pertaining to the free movement of goods must follow; and agreement is now reached by weighted majority voting. Directives of this type are now known as *Article 100A Directives*, and the framework structure as the *New Approach*.

At this point it should be noted that although the primary intention is to secure free circulation to goods etc. within and between the Member States, there are no intention of creating a "fortress Europe". Non-European Union manufacturers are at liberty to comply with Article 100A Directives and so claim free entry to the European market. Indeed once a Directive has entered fully into force all goods entering the European Union (EU) **MUST** comply with the relevant requirements. Where a Directive allows manufacturer self-certification, this may be done by a non-EU manufacturer as well as by an EU one. However, the agent within the EU, or the person actually introducing the article into the EU, is held to be responsible for compliance. In the case of Directives requiring certification by an independent body (notified body) such bodies can only be centered within the EU, and non-EU manufacturers would have to seek certification from one such body. However, being centered in the EU does not prevent such bodies having agents in non-EU states who can do the actual work of assessment, providing the bodies central unit takes full responsibility.

With its network of offices, LR is ideally suited to offer such a certification service to non-EU manufacturers.

1.2 The New Approach

The framework structure known as the *New Approach* is to be found in the Council Resolution of May 1985, and is in the form of model articles to be used to construct Directives. Broadly these model articles fall into two categories: a set of standard

administrative requirements that can appear almost unchanged in nearly every Directive; and three or four clauses that have to be specifically tailored to the particular Directive. It is necessary to look at this situation in a little more detail.

1.2.1 The standard administrative clauses cover such aspects as:

- (i) The requirement that Member States must allow free access to their market of items that comply with the Directive.
- (ii) The general requirement that items covered by the Directive must be safe. This is in a sense an escape clause against some particular technical aspect having been overlooked in the list of essential technical requirements [see Section 1.2.2(ii)].
- (iii) The general requirement that all items must satisfy the essential technical requirements. However it is recognised that for Directives with a wide scope [e.g. the Machinery Directive see Section 2.2.3] not all the essential requirements will be appropriate to all items.
- (iv) A concession to Member States to refuse free access [see Section 1.2.1(i) above] if they seriously doubt the general safety [see Section 1.2.1(ii) above] of the item. This concession is accompanied by the obligation to submit such a refusal to arbitration by the Commission and other Member states.
- (v) The relationship between the essential requirements and the use of standards [see Section 1.4 for more details].
- (vi) The right of Member States to appoint organisations to act as certifying bodies; and the criteria by which such bodies shall be judged before being appointed.

1.2.2 The specific clauses cover such aspects as:

(i) The Scope

Which has to be the best possible description of the items to which the Directive applies; although in some cases the matter is handled by a fairly general description qualified by specific exclusions i.e. listing the items to which it does not apply. The scope is frequently a matter of considerable dispute during the negotiating phase, and often subject to political pressure by organisations who do not wish to see long-standing legal requirements changed. However, the scope is absolutely crucial to the success of a Directive in removing barriers to trade. For one thing it is very difficult to decide which requirements are essential until the items to be covered are established, and in practice it is not uncommon for the negotiation of the scope and the essential requirements to form something of an iteration. This process can sometimes lead to the scope being less than crystal clear. An unfortunate situation because this in turn can lead to ambiguity when the Directive comes to be used.

(ii) The Essential Technical Requirements

When the philosophy of the *New Approach* was being formulated it was agreed that the essential requirements should be couched in terms of the aims to be achieved, rather than in terms of absolute technical specifications. The argument being that designers should be allowed the maximum flexibility if the

development of new products and techniques was not to be stifled. In contrast most Member State regulations are cast in terms of specific solutions. However, their legal systems allow administrators to grant concessions when a particular specific solution is considered to be inappropriate giving flexibility. UK law on the other hand does not allow such discretion, and therefore has to be cast in a form that gives "built-in" flexibility. This fact means that the UK system is close to the New Approach philosophy, but at negotiating level this causes problems when the officials of some Member States are extremely reluctant to give up their apparent absolute solutions in exchange for much more general aims. The result is that some Directives end up with an unhappy mix of general aims and specific solutions.

(iii) Certification of Conformity Procedures

For the first few New Approach Directives these procedures were individually negotiated, and this proved to be a very time consuming process. The basic problem was that individual Member States had conformity procedures that had served them well for many years, and were consequently very reluctant to change to any other system.

An attempt to tackle this problem was made in the 1990 Modules Decision – 90/683/EEC – in which all the existing procedures were consolidated into a menu of individual units. These units could then be combined for individual Directives in a variety of ways to build suitable conformity procedures, the most suitable combination – or combinations – being a matter of negotiation between the Member States. The latest version of the modules appears in Council Decision 93/465/EEC.

Because many of the barriers to trade lay in the diversity of conformity procedures used throughout the Member States, this aspect of a Directive is vital to its success.

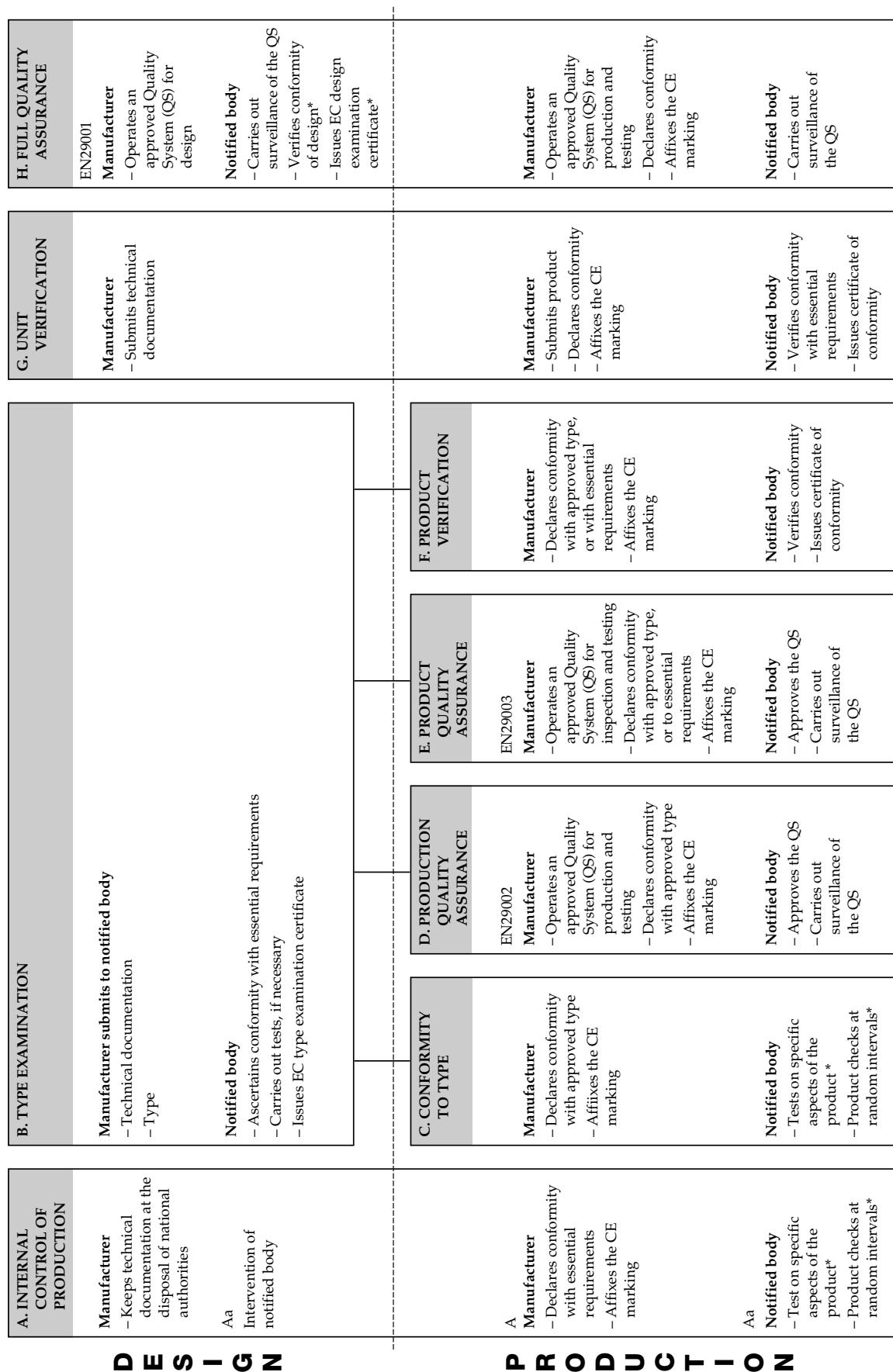
In view of its relevance to the work of Lloyds Register it is worth making a more detailed study of the Modules.

1.3 The Modules

Two basic principles were recognised in constructing the menu of modules. Firstly that there was a necessity to consider products initially at the design stage, followed by checking that the initial design was faithfully reproduced in the production stage. Secondly that responsibility for checking at both stages could range from resting entirely with the designer/manufacturer, to resting entirely with an independent third party. Additionally it was recognised that the extent to which a designer/manufacture had satisfied formal quality management criteria (QM) must be taken into account if the value of QM approval was not to be downgraded.

Upon these two basic principles two other factors imposed themselves. The first was that a system suitable for mass produced items would be different from that suitable for one-off, or limited, production. The second was that account must be taken of the commercial cost of conformity assessment, balancing it against the capital cost of the product and the degree of danger presented by the product.

The resulting solution to this set of requirements is neatly summarised by the now widely circulated "Conformity Assessment" diagram that is reproduced in Figure 1.



*Supplementary requirements which can be used in specific directives.

Figure 1
Conformity Assessment Procedures in Community Legislation
“The Modules”

The horizontal divide separates the design from the production stages.

In the design stage above the horizontal line and reading from left to right, the range covers:

- responsibility resting squarely upon the designer,
- through the situation applicable to mass produced items where an independent body can approve a prototype,
- through the situation where one-off items are independently approved,
- finally to the situation where the responsibility again rests with the designer, but only on condition that there is independent approval and surveillance of the designers' quality management system.

Moving below the horizontal line into the production stage, the extreme ends mirror the design stage:

- the extreme left placing responsibility on the manufacturer,
- the extreme right doing the same thing but under conditions of independent QM approval,
- There is however on the right hand end a third option of requiring independent approval of each production item. These three procedures – designated modules A, H and G respectively – cover both design and manufacturing stages.

Returning to the middle of the diagram it is permitted to use the design type examination process – Module B – in conjunction with four possible production stage procedures to ensure each product is in conformity with the approved prototype. Again reading from left to right we have:

- Module C where it is the manufacturer's responsibility to ensure conformity with the approved prototype,
- Modules D and E where it is again the manufacturer's responsibility but under conditions of independent QM approval for manufacture and testing, or inspection and testing respectively; finally,
- Module F where the responsibility rests with independent approval of each item of production.

Unfortunately, even at the outset, this fairly straightforward menu of attestation procedures was clouded with variations within modules. In particular:

- Module A could become Aa in which there will be a degree of third party intervention in respect of specific aspects of design and production. These aspects would be designated in the text of the Directive.
- Module C could have a similar variation by which there is independent intervention during the manufacturing stage in respect of specifically named aspects.
- Module H could also require independent intervention during the design stage in respect of specifically named aspects.

Unfortunately the question of variations is still very much alive and in recent months further modifications have been proposed in respect of the Pressure Equipment Directive currently under negotiation. The real trouble is that independent intervention in the area of pressure vessels is wide spread throughout the Member States, of long standing, and very variable in the way it is done. The negotiations are being made very difficult by Member States seeking to retain their own specialist methods. Furthermore the administrative text of the original Modules Decision recognised that variations might be necessary in

certain circumstances, but warned that such variations should be strictly limited and made only when they could be justified. Regrettably some Member States consider that their current practice is sufficient justification for such variations!

It will be sad if this proliferation of variants is allowed to take root because it could destroy what is at present a reasonably elegant solution, by virtually returning to a free for all in the negotiation of conformity assessment procedures.

Because of all this it has to be warned that the use of the modules for establishing conformity assessment is at best a fragile system. Many of the early New Approach Directives do not use them because they predate the Decision, and although what is required may look very like specific modules, careful reading of the wording of the individual Directive texts will show significant differences. To an extent common sense would suggest that the early New Approach Directives should be revised to use the modules. Practical experience dictates that once adopted, leave well alone, because once change is suggested in one aspect Member States will seek to fight once again battles they lost first time around, and before anybody realizes it, the complete Directive is being renegotiated. Fortunately at least the Commission accepts that any attempt to reshape such recent legislation could be disastrous to industry.

1.4 The Role of Standards in Directives

This is arguably one of the most widely misunderstood aspects of the Directive scene. There is a tendency to assume that Directives require the products covered to be designed exclusively to recognised European standards. This is quite incorrect. The law requires that the essential requirements listed in Directives must be complied with. The use of standards is one means of demonstrating compliance with these requirements, but not the only means.

The New Approach Resolution makes it very clear that Directives should require compliance with essential requirements, which should be formulated in terms of the objectives to be obtained and not the techniques for achieving them. However the Resolution went on to recognise the value of standards that give prescriptive solutions, and strongly encouraged their use, providing it was recognised that they may not represent the only solution and indeed, on occasions, not necessarily the most appropriate solution.

As a consequence of recognising the value of standards a system was devised by which the European Commission may mandate the European Standards bodies – CEN/CENELEC/ETSI – to produce standards in support of specific Directives. In such a mandate the demand would be that the essential requirements listed in the Directive should form the technical criteria on which the standard must be based. In giving such a mandate the Commission allows the standard makers a very considerable degree of freedom on such aspects as the subject matter, the form, the technical content, and the relationship with other standards. It does however insist that the standard shall not make requirements over and above the essential requirements, and shall not stray into the aspect of who shall carry out any testing or inspection deemed necessary. This latter aspect is the strict preserve of the Directive text.

Standards that have been mandated by the Commission will eventually be checked by it, in conjunction with a Committee of Member State representatives. This is to ensure only that the scope claimed is covered, that it has not strayed beyond the essential technical requirements nor has specified who shall carry out inspections or tests. However there will be no question of rediscussions of the technical aspects. In other words no attempt by Commission "experts" to "second-guess" the standards experts.

If found to be satisfactory the title of such standards will be published in the Official Journal of the European Communities (O.J.), and this will complete the process of creating what is termed Harmonised Standards. Whilst it should be noted that an existing CEN/CENELEC/ETSI standard can be turned into a harmonised standard in retrospect – if it is considered suitable – it must be clearly understood that not all CEN/CENELEC/ETSI standards are harmonised standards.

Once a standard has become a “harmonised standard” its use for design and manufacture will automatically confer a “presumption of compliance” with the appropriate essential requirements of the Directive. Standards which are not “harmonised” do not give such automatic presumption, although the technical requirements of many standards may well satisfy essential requirements. The essence of this philosophy is that because the specification for the writing of a harmonised standard is a set of essential requirements already agreed by Member States, and because the finally agreed standard represents what might be described as the collective wisdom for achieving the desired aim, the standard therefore represents a solution agreed by all Member States. However, it is not necessarily the only solution, so it might be an exaggeration to say it represents the best solution in all cases. What can be said is that the use of a harmonised standard by the manufacturer is the method least likely to be challenged by any Member State authority.

At this point it is worth noting some interesting variations in approach by standard writers in different fields. The most common approach is to produce as nearly as possible self-standing standards for the range of products covered by a particular Directive. This has been the approach for the Simple Pressure Vessels Directive.

However for the Machinery Directive a complex structure of three levels is being followed because of the very wide range of products covered. The first (top) level comprise the so called “A” standards which are by way of general codes of practice for the design of safe machinery. The second level – the “B” standards – fall into two sub-categories – “B1” and “B2” – covering respectively; human factors, such as arm reach, safe noise levels, etc.; and the design of specialist safety devices such as pressure-mats, electronic cut-outs, etc. Finally come the “C” standards which deal with specific families of machinery, and which make reference to appropriate use of the “A” and “B” standards. For this Directive it is only the “C” standards that carry the ‘presumption of conformity’ with the Directive.

Yet another approach is being used for the Recreational Craft Directive where certain of the standards are being written at international level, and will be adapted – probably without further discussion – as CEN standards for the purpose of harmonisation.

During the negotiation of Directives there has been a move towards encouraging the use of harmonised standards by offering an “easier” conformity assessment route; that is to say one that involves less involvement by an independent body – when such a standard is used than when it is not. A good example of this is the Machinery Directive in which there is a list of what are considered to be particularly dangerous machines, Annex IV of the Directive. If the items on this list are not manufactured to the appropriate harmonised standard the design has to be independently Type Approved, whereas if the harmonised standard is used conformity can be declared by the designer/manufacturer.

The outcome of this policy of mandating the writing of standards has resulted in an enormous programme for the CEN, CENELEC and ETSI organisations and a very demanding work load on the people involved in actually producing the texts. Moreover the Commission is finding it increasingly difficult to meet its financial commitment to this programme.

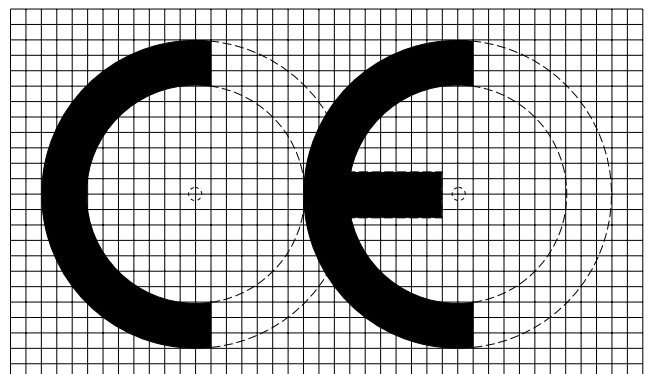
1.5 CE Marking

The use and purpose of the “CE” mark is frequently looked upon as something of a mystery. Its purpose is very simple. It is purely a symbolic statement that the person marketing the item considers that it complies with all the requirements of a Directive. It could be held to duplicate the Certificate of compliance required by most new approach Directives. Its intended usefulness is far less clear!

From the very early days of the Community, Article 100 Directives have required the products covered to be marked with a symbol denoting compliance. These early marks were of a wide variety of forms, and in some instances attempted to have variants denoting such differences as, for example, whether or not a European Standard had been used. The whole system became very complicated, and the producers of the new approach decided to adopt a single unified design of mark – the CE mark – to be used in all instances and for all new Directives. The attempt was partially successful in that the CE mark was universally used, but had certain variations, Directive to Directive, such as adding the date on which the mark was applied and sometimes the identification number of any notified body involved.

It took a second attempt at unification – the CE Marking Directive 93/68/EEC – to bring the situation under control. This Directive modified the CE marking requirements of all the previously adopted new approach Directives and in some instances slightly modified the actual conformity procedures. The outcome is that the CE mark now has a defined form in terms of the shape and spacing of the two letters, and the requirement that it must not be less than 5mm in vertical height. Its construction is given in Directive 93/68/EEC and is shown in Figure 2 and is mandatory from 1 January, 1997. Furthermore, the marking of a product with this symbol is now held to indicate that it conforms to the requirements of all applicable Directives that specify the use of such a mark. However should one or more of these Directives be still in the transition phase – i.e. the supplier has the option of complying or not – the accompanying documentation must say whether or not it is being complied with.

The CE conformity marking consists of the initials ‘CE’ as shown below. The proportions shown must be retained when the marking is reduced or enlarged. The initials are formed from two overlapping circles of 20mm diameter and 14mm diameter.



Note 1: CE MARKING DIRECTIVE 93/68/EEC is mandatory from 1 January 1997. The Directives it amends are given in the reference 4.3.2.

**Figure 2
CE Marking**

Turning now to the question of the usefulness of CE marking, clearly it should indicate to an official of a Member State that the item claims compliance with EC Directives at the instance it is placed onto the market. But as all such items must comply by law – assuming the Directives are fully in force – the mark appears to be saying no more than that the item complies with the law. A statement of rather doubtful value. Similarly, if the item has been in use for some time, all the mark indicates is that it claimed compliance with the law at the time when it was first sold. Again a statement of doubtful value to an inspector concerned with the safety of the item at the present time.

Probably only time will tell how useful the CE mark will prove to be from a marketing or regulatory point of view. Perhaps the best that can be said at the moment is that it will act as a passport for new items entering individual Member States.

2. SUMMARIES OF SELECTED DIRECTIVES

2.1 Simple Pressure Vessels Directive (SPV)

2.1.1 General

The Simple Pressure Vessels (SPV) Directive is one of the first “New Approach” Directives designed to harmonise the approval methods used throughout the European Member States. The Directive 87/404/EEC, as amended by Directive 90/488/EEC and 93/68/EEC Article 2, came into force on 1 July 1990, and became mandatory on 1 July 1992. It was transposed into UK law by Statutory Instrument (SI) 1991 No. 2749 and by corresponding legislation in other Member States.

2.1.2 Definition

A Simple Pressure Vessel is defined as any welded vessel subjected to an internal gauge pressure greater than 0.5 bar which is intended to contain air or nitrogen and which is not intended to be fired. Furthermore the vessel must be:

- made either of non-alloy quality steel or non-alloy aluminum or non-age hardening aluminum alloy,
- either cylindrical closed by flat or outwardly dished ends, or two dished ends set on the same axis,
- designed for a maximum working pressure no greater than 30 bar gauge and a stored energy capacity of no greater than 10,000 bar litre,
- designed for a minimum working temperature no lower than -50°C, and a maximum working temperature no higher than 300°C for steel and 100°C for aluminum,

Excluded from the definition are vessels:

- specifically designed for nuclear use failure of which would cause an emission of radioactivity,
- vessels specifically intended for installation in or propulsion of ships and aircraft,
- fire extinguishers.

2.1.3 Directive Requirements

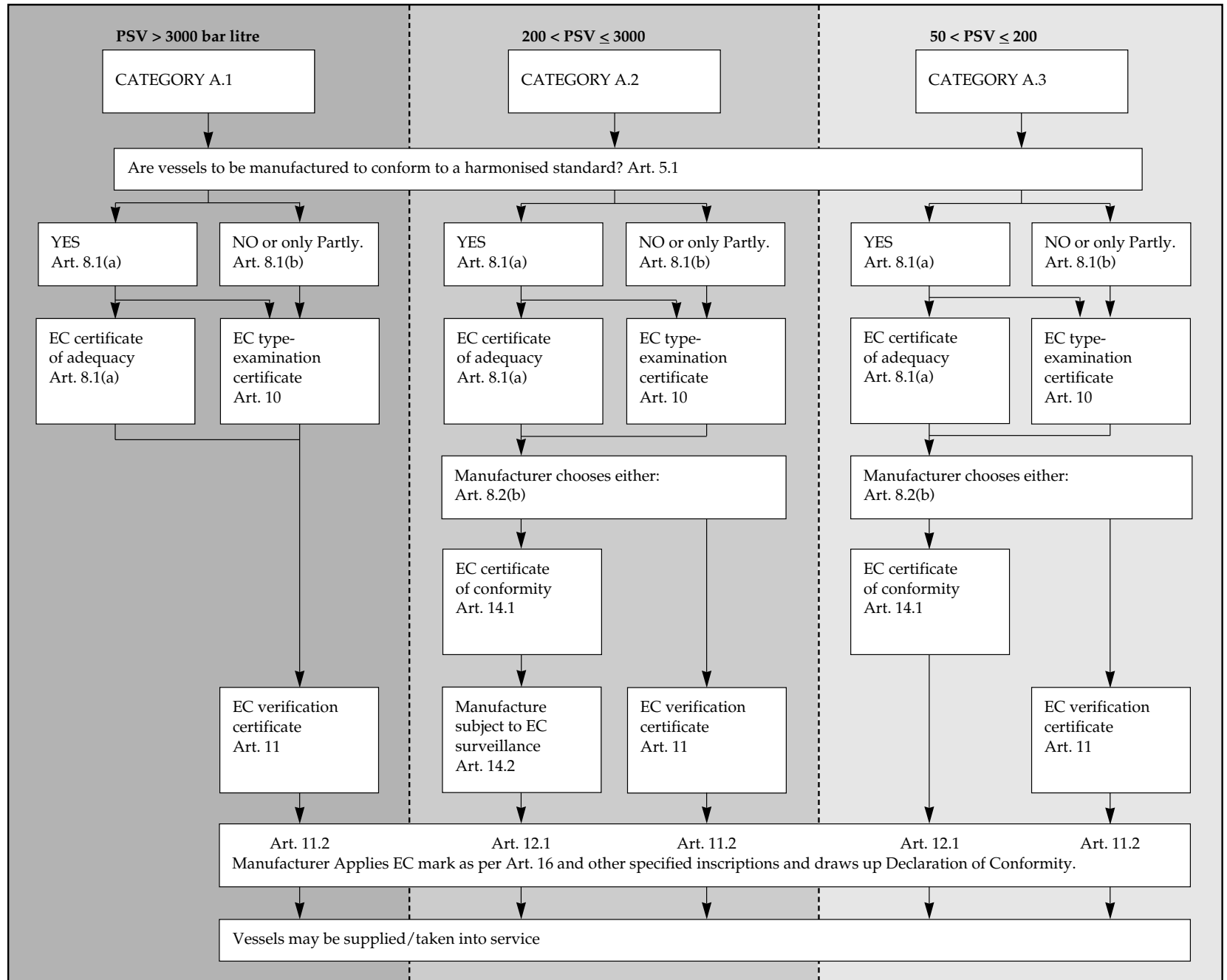
These are referred to as “the essential safety requirements” (ESR) and are to be found in Annex I of the Directive. Although this is one of the new approach Directives the ESR’s do not fully follow the philosophy of stating the aims to be achieved rather than the way in which to achieve them. In consequence the Directive has quite specific material requirements in respect of chemical composition and mechanical properties. This has proved to be a particularly unfortunate factor as very few commonly used steels actually meet the requirements forcing the use of more sophisticated and hence most costly steels. However apart from this one area the ESR’s relate to such matters as use of correct welding materials and accessories contributing to the strength of the vessel; protection from corrosion; adequate wall thickness; ability to inspect internally; and use of manufacturing procedures that do not weaken the materials.

It requires the manufacturer to produce a design and manufacturing schedule, adequate instructions for use, and to mark the vessel with information on working pressures and temperatures.

2.1.4 Routes to Attestation

In view of the fact that the negotiation of this Directive predated the Modules Decision, the attestation procedures are unique to the Directive. They are shown in diagrammatic form

Figure 3
Simple Pressure Vessels Directive
Certification Route



in Figure 3 and are based on the philosophy that the higher the stored energy – indicated by the product of volume and working pressure – the greater the danger present, and hence the greater the intervention necessary from the Approved Inspection Body (AIB).

For vessels of less than or equal to 50 bar litre the manufacturer may self certify that the design and manufacture is to “sound engineering practice”. There is no call for them to specifically meet the ESR’s. However for all vessels greater than this the design must be approved by an AIB as meeting the ESR’s either by assessment of a prototype, or, if the design is to a harmonised standard, by assessment of the design and manufacturing schedule.

For the production phase there is a further change of requirement at 200 and 3,000 bar litre. For vessels between 50 and 200 bar litre the manufacturer must obtain AIB approval of the manufacturing schedule but retains responsibility for quality control during manufacture. For vessels between 200 and 3,000 bar litre the manufacturer may choose either the full verification route, or a route by which the AIB approves the manufacturing schedule and then carries out quality control by means of spot checks. For vessels above 3,000 bar litre there must be full AIB verification of each vessel.

2.1.5 CE Marking

CE Marking is required on all vessels greater than 50 bar litre. Vessels below 50 bar litre are covered by the Directive and must be allowed free circulation providing the manufacturer can confirm that they are produced to “sound engineering practice” despite not carrying the CE Marking.

Until 1 January 1997 the manufacturer has the choice of complying either with the CE marking requirements in the original Directive 87/404/EEC [Article 16] or the amended version as per Directive 93/68/EEC [Article 2 paragraphs 8, 9 and 10]. The requirements for CE Marking as given in Directive 93/68/EEC is mandatory from 1 January 1997 (see Figure 2).

2.1.6 LR Involvement as a Notified Body

As one of the UK Bodies notified under the Directive LR has been involved in the issue of certificates covering both the design and manufacturing stages. Indeed it is estimated that 85% of the UK business has come to LR.

When the Directive first came into force this certification work was made difficult by the lack of harmonised standards. Manufacturers were obliged to seek certification to the essential requirements and notified bodies were faced with the problem of making interpretations of the essential requirements. This proved particularly difficult in respect of such requirements as “it must be possible to inspect the inside of the vessel”; and in establishing the actual chemical composition and properties of certain steels.

However LR helped many companies overcome these problems and 1993 and 1994 saw a steady stream of certification work coming from four UK manufacturers. A manufacturer in the USA and one in Finland have also received certification from LR.”

2.2 Machinery Directive (MD)

2.2.1 General

The Machinery Directive (MD) is a ‘New Approach’ Directive intended to harmonise the various legal requirements relating to the adequate safety of new machinery, in force in individual European Member States. The Directive 89/392/EEC, as amended by Directive 91/368/EEC came into force on 1 January

1993, and became mandatory on 1 January 1995. It was transposed into UK law by Statutory Instrument [SI] 1992 No. 3073. A second amendment Directive 93/44/EEC came into force on 1 January 1995 and becomes mandatory on 1 January 1997. It was transposed into UK law by SI 1994 No. 2063. Directive 93/68/EEC Article 6 amends the CE Marking.

2.2.2 Definition

It was originally intended that one Directive should cover very nearly all machinery accordingly the definition is worded in a very general way. It is:

“An assembly of linked parts or components at least one of which moves, with the appropriate actuators, controls and power circuits etc., joined together for a specific application.”

As a result the Directive, as extended by the two amending Directives, covers a vast range of manufacturing, mobile and lifting equipment (including domestic appliances), agricultural machinery and off road vehicles; together with certain items that are not strictly machines as defined above but are designed specifically for use with machines, e.g. safety devices, lifting slings etc.

The following items are excluded from the scope:

- passenger lifts,
- machinery, other than lifting equipment, that is manually powered,
- medical machinery used in direct contact with the patient,
- specialist fairground and amusement park equipment,
- steam boilers, tanks and pressure vessels,
- specialist nuclear equipment, failure of which may result in an emission of radioactivity,
- radioactive sources forming part of a machine,
- firearms,
- storage tanks and pipelines for inflammable liquids and dangerous substances,
- means of transport for passengers,
- seagoing vessels and mobile offshore units,
- cableways and rack and pinion rail mounted vehicles,
- certain agricultural and forestry tractors,
- machinery specifically designed for military or police purposes,
- mine winding gear,
- theatre elevators,
- construction site hoists for persons.

2.2.3 Directive Requirements

The vast majority of the technical requirements are set in terms of the hazards to be avoided. As a consequence all manufacturers are first required to carry out a hazard analysis with the purpose of, if possible, eliminating the hazard; or, failing that, take steps to guard against it; or, if neither is possible, warn against in the instruction manual.

The Directive text recognises that it is not always technically or commercially possible to make a machine completely safe, so that the UK philosophy of “in so far as is reasonably practicable” is preserved.

2.2.4 Routes to Attestation

This Directive again pre-dates the Modules Decision so that the Modules A, B, C, etc., do not appear in the text. However the vast majority of equipment covered is attested as meeting the requirements of the Directive by the manufacturer or person placing the equipment on the market, which is closely akin to Module “A”. The exception is a restricted list of machines that

are considered to be particularly dangerous (mainly hand fed woodworking machinery, metal presses and injection molding machines) which appear in Annex IV of Directive 89/392/EEC. The design of these machines requires type approval by a Notified Body, which is akin to Module “B”, unless a harmonised standard is used, in which case the manufacturer may merely lodge the technical file with a Notified Body. Reference Figure 4.

2.2.5 CE Marking

CE marking is required on all machines covered by the Directive as an indication that the machine meets not only the requirements of the Machinery Directive, but also the requirements of all other Directives that apply. However it has been recognised that certain machinery can quite reasonably be placed on the market with the intention of incorporating it into other machinery. Under these circumstances such machinery may not completely meet all the Directive requirements until it has been correctly incorporated. Such machinery is not CE marked, but is required to have a “Certificate of Incorporation”

explaining in what way it must be installed in order to ensure complete compliance.

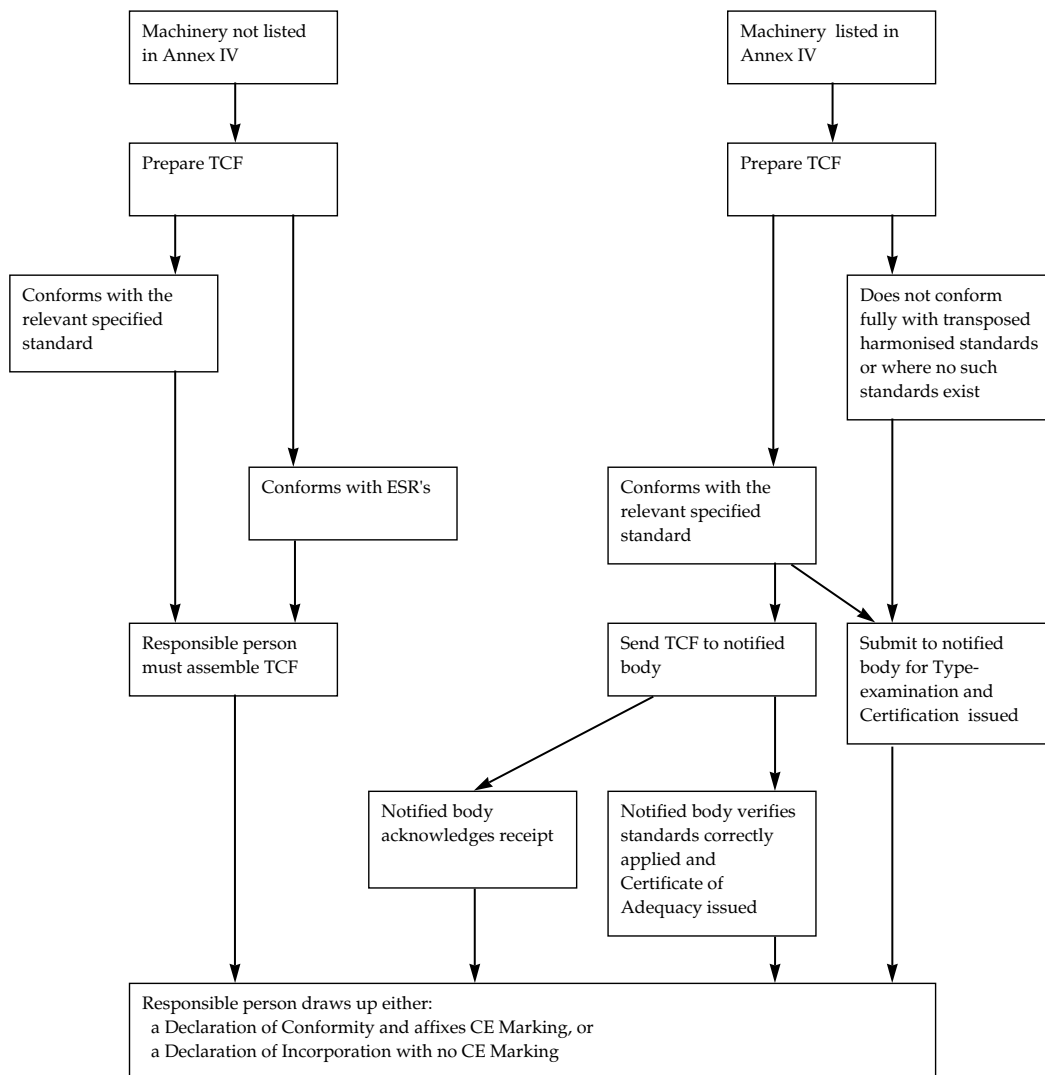
Note:

Certain *safety components* are listed in Annex IV of the Directive for these components the CE marking is **not affixed**.

2.3 Recreational Craft Directive (RCD)

2.3.1 General

The Recreational Craft Directive (RCD) is one of the latest “New Approach” Directives designed to harmonise the laws of Member States in respect of ensuring the safety of boats when they are first placed on the Community market. The Directive 94/25/EC comes into force on 16 June 1996, and becomes mandatory on 16 June 1998. The Directive has not yet been transposed into UK law, but the scheduled date is 16 December 1995.



Note 1:

All machinery must satisfy the essential health and safety requirements (ESR'S).

Note 2:

For machinery not listed in Annex IV, a manufacturer may, if he so desires, use the services of a third party with his demonstration of compliance to the directive.

Figure 4
Machinery Directive
Procedures for Attestation

2.3.2 Definition

The Directive covers recreational craft, regardless of means of propulsion, from 2.5 to 24 metres hull length. It also covers the following components when they are placed separately on the market:

- ignition protection equipment;
- start-in-gear protection equipment;
- steering wheels, mechanisms and cable assemblies;
- fuel tanks and hoses;
- prefabricated hatches and portlights.

It excludes:

- craft intended for racing
- canoes, kayaks, gondolas and pedalos
- sailing surfboards
- powered surfboards, and replicas of historic craft designed before 1950
- experimental craft
- craft built for own use providing they are not placed on the market during a period of five years
- craft specifically intended to be crewed and to carry passengers,
- submersibles, air cushion vehicles and hydrofoils.

2.3.3 Directive Requirements

These are generally expressed in terms of hazards to be avoided, e.g. lack of strength, stability and buoyancy; flooding; fire; explosion; etc. – together with absolute requirements for hull identification; a builder's plate; and an owner's manual drawing particular attention to risks of fire and flooding. There are also requirements in respect of navigation lights and pollution prevention.

It also requires the manufacturer to produce a design and manufacturing schedule (the technical file).

2.3.4 Paths to Attestation

Negotiation of this Directive post-dated the Modules Decision and as a result extensive use is made of the modules. The finally agreed procedures are based on a relationship between boat length and the sea and wind conditions that the boat is designed to withstand. These are shown diagrammatically in Figure 5. The range is from self certification by the manufacturer, to type approval coupled with product or quality management verification by a Notified Body.

A certain degree of incentive is given to the use of harmonised standards by reducing the degree of Notified Body intervention, but not to the same extent as in the Machinery Directive.

2.3.5 CE Marking

The adoption of this Directive post-dated the CE Marking Directive 93/68/EEC so that the CE marking requirements align with it. All boats and components falling within the scope must carry the CE mark denoting conformity with the RCD and with any other Directive that is applicable. Partially completed boats may be placed on the market, but without being CE marked, providing they are accompanied by a declaration that they are intended to be completed by others, together with a statement of the essential requirements already complied with.

The components covered by the Directive require to be both CE marked and accompanied by a Declaration of Compliance.

2.4 Personal Protective Equipment Directive (PPE)

2.4.1 General

The Personal Protective Equipment (PPE) Directive is one of the 'New Approach' Directives, prepared to standardise the approval methods used throughout the European Member States. The Directive 89/686/EEC came into force on the 1 July 1992 being mandatory from 1 July 1995 and was amended by Directive 93/95/EEC and Directive 93/68/EEC Article 7.

Design Category	Modules to be used	
A "Ocean"	Aa	B + C or B + D or B + F or G or H
B "Offshore"		
C "Inshore"	If harmonised standard used for stability and buoyancy assessment	A
	If harmonised standards are not used	Aa
D "Sheltered Waters"	A	
	2.5	12
	Boat Length (Metres)	
		24

Figure 5
Recreational Craft, Modules for Attestation

It was transposed into UK law by Statutory Instrument (SI) 1992 No. 3139 and SI 1993 No. 3074.

2.4.2 Definition

PPE is defined as “Any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards”. It also covers combinations of PPE, combinations with personal non-protective equipment and interchangeable PPE which provides protection against one or more hazards simultaneously.

2.4.3 Categories

The directive categorises PPE into three groups for the Attestation (approval route) by which compliance with the Directive may be demonstrated. The different categories are Simple Design, Complex Design or neither Simple or Complex Design:

(i) *Simple Design*

PPE Models of *SIMPLE* Design are ones where the designer assumes the user can himself assess the level of protection against the minimal risks concerned, the effects of which, when they are gradual, can be safely identified by the user in good time. Article 8.3 of the Directive. This category covers exclusively PPE intended to protect the wearer against:

- mechanical action whose effects are superficial (gardening gloves, thimbles, etc.),
- cleaning materials of weak action and easily reversible effects (gloves affording protection against diluted detergent solutions, etc.),
- risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50°C or to dangerous impacts (gloves, aprons for professional use, etc.),
- atmospheric agents of neither exceptional nor extreme nature (headgear, seasonal clothing, footwear, etc.),
- minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (light anti-scalping helmets, gloves, light footwear, etc.),
- sunlight (sunglasses).

(ii) *Complex Design*

PPE Models of *COMPLEX* Design are designed to protect against mortal danger or against dangers that may seriously and irreversibly harm the health, the immediate effects of which the designer assumes the user cannot identify in sufficient time. [Article 8.4(a) of the Directive]. This category covers exclusively:

- filtering respiratory devices for protection against solid and liquid aerosols or irritants, dangerous, toxic or radiotoxic gases,
- respiratory protection devices providing full insulation from the atmosphere, including those for use in diving,
- PPE providing only limited protection against chemical attack or against ionizing radiation,
- emergency equipment for use in high temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of large amounts of molten material,
- emergency equipment for use in low temperature

- environments the effects of which are comparable to those of an air temperature of -50° C or less,
- PPE to protect against falls from a height,
- PPE against electrical risks and dangerous voltages or that used as insulation in high tension work.

(iii) *Neither Simple or Complex Design*

This covers all *PPE Models* which do not fall into the categories of either Simple or Complex Design.

2.4.4 Exemptions

Some PPE are exempt from complying with the Directive. These primarily cover PPE which is for use by, e.g.:

- the armed forces,
- self defence,
- general private use, e.g. umbrellas, general purpose gloves, etc. ,
- second hand PPE,
- motorbike helmets, etc.

2.4.5 Directive Requirements

These are referred to as the basic health and safety requirements (BHSR) and are to be found in Annex II of the Directive. The following list gives an indication of the typical areas covered by the BHSR:

- design,
- comfort and efficiency,
- impact,
- falls,
- slippage,
- ageing,
- respiratory,
- visibility protection of various body parts,
- drowning,
- noise,
- heat and/or fire,
- cold,
- electric shock,
- radiation,
- dangerous substances,
- diving etc.

The information to be supplied by the manufacturer of PPE products which are offered for use on the market, is also covered, e.g.:

- name and address of the manufacturer and/or his authorised representative established in the Community,
- storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions,
- performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question,
- suitable PPE accessories and the characteristics of appropriate spare parts,
- the classes of protection appropriate to different levels of risk and the corresponding limits of use,
- the obsolescent deadline or period of obsolescence of PPE or certain of its components,
- the type of packaging suitable for transport,
- the significance of any markings.

The above notes must be precise and comprehensible and must be provided at least in the official language(s) of the Member State of destination.

2.4.6 Routes to Attestation

The paths by which the manufacturer may demonstrate his products compliance with the requirements of the Directive are detailed in Figure 6. The route available is dependent on the product's category.

These may be summarised as follows:

- **General**

This section is applicable for all PPE covered by the Directive. The manufacturer carries out a risk assessment to determine the hazards against which his product will offer protection. He then identifies the applicable BHSR of the Directive with which to comply which is assembled in a technical document

- **Simple Models**

Once the general requirements are satisfied, the manufacturer prepares and signs his Declaration of Conformity and affixes the CE Marking to the product or packaging.

- **Neither Simple or Complex Models**

After completing the general requirements, the manufacturer submits his application for an EC Type Examination to a Notified Body.

The application must contain the following information:

- the name and address of the manufacturer or his authorised representative,
- the name and address of the PPE production plant,
- the manufacturer's technical documentation/file.

The Notified Body carries out the following:

- review of the manufacturer's technical file,
- verification that the model is produced in accordance with the submitted documentation,
- examination and tests to verify that model(s) satisfy the requirements,
- on satisfactory completion, issue an EC Type Examination Certificate.

The manufacturer then prepares and signs his Declaration of Conformity and affixes the CE Marking to the product or packaging.

- **Complex Models**

The procedure is the same as the *Neither Simple or Complex Models* with the addition of monitoring of the manufacturing process to confirm that the production model is in conformance with that described in the EC Type Examination Certificate. The manufacturer may use the same Notified Body which carried out the EC Type Examination for this monitoring phase, if suitably approved, or another suitably approved Notified Body of his choice.

The manufacturer has the choice of two monitoring procedures:

- (a) 'EC' quality control system for the final product.

This system consists of monitoring by taking randomly selected samples for examination and testing as per the harmonised standard. These checks are carried out at random, normally at intervals of at least one year.

or

- (b) 'EC' quality of production by means of monitoring.

This consists of an initial review of the documentation and an audit of the manufacturer's production quality control system including the relevant examinations and tests of the PPE models; followed by surveillance.

2.4.7 CE Marking

Until 1 January 1997, the manufacturer has the choice of two forms of CE Marking, the original as per Directive 89/686/EEC (Article 13 and Annex IV) or the amended version as per Directive 93/68/EEC (Article 7, Paras 6 and 8). From 1 January 1997, only that given in Directive 93/68/EEC can be used.

2.5 Electromagnetic Compatibility (EMC) Directive

2.5.1 General

The Electromagnetic Compatibility (EMC) Directive 89/336/EEC as amended by 91/263/EEC(*), 92/31/EEC and 93/68/EEC (Article 5) is a 'New Approach' Directive. The Directive applies to all electrical and electronic appliances or systems, together with equipment and installations containing electrical and/or electronic components, which are liable to cause electromagnetic disturbance or the performance of which is liable to be affected by such disturbances.

The EMC Directive came into force on the 1 January 1992 and is mandatory from 1 January 1996. It was transposed into UK Law by Statutory Instruments (SI) 1992 No. 2372 and SI 1994 No. 3080.

Note:

91/263/EEC is the Telecommunications Terminal Equipment (TTE) Directive. It covers the EC Type Examination of TTE and cancels Article 10(4) of the EMC Directive. i.e. Type approval of TTE previously covered by Directive 86/361/EEC.

From 1 January 1992, the EMC Directive repeals the following 'Old Approach' Directives:

- | | |
|------------|--|
| 76/889/EEC | Radio interference caused by electrical household appliances, portable tools and similar equipment, |
| 76/890/EEC | Suppression of radio interference with regard to fluorescent lighting luminaries fitted with starters. |

2.5.2 Definitions

- **Apparatus**

means all electrical and electronic appliances together with equipment and installations containing electrical and/or electronic components.

- **Electromagnetic Disturbance**

means any electromagnetic phenomenon which may degrade the performance of a device, unit of equipment or system. An electromagnetic disturbance may be electromagnetic noise, an unwanted signal or a change in the propagation medium itself.

- **Immunity**

means the ability of a device, unit of equipment or system to perform without degradation of quality in the presence of an electromagnetic disturbance.

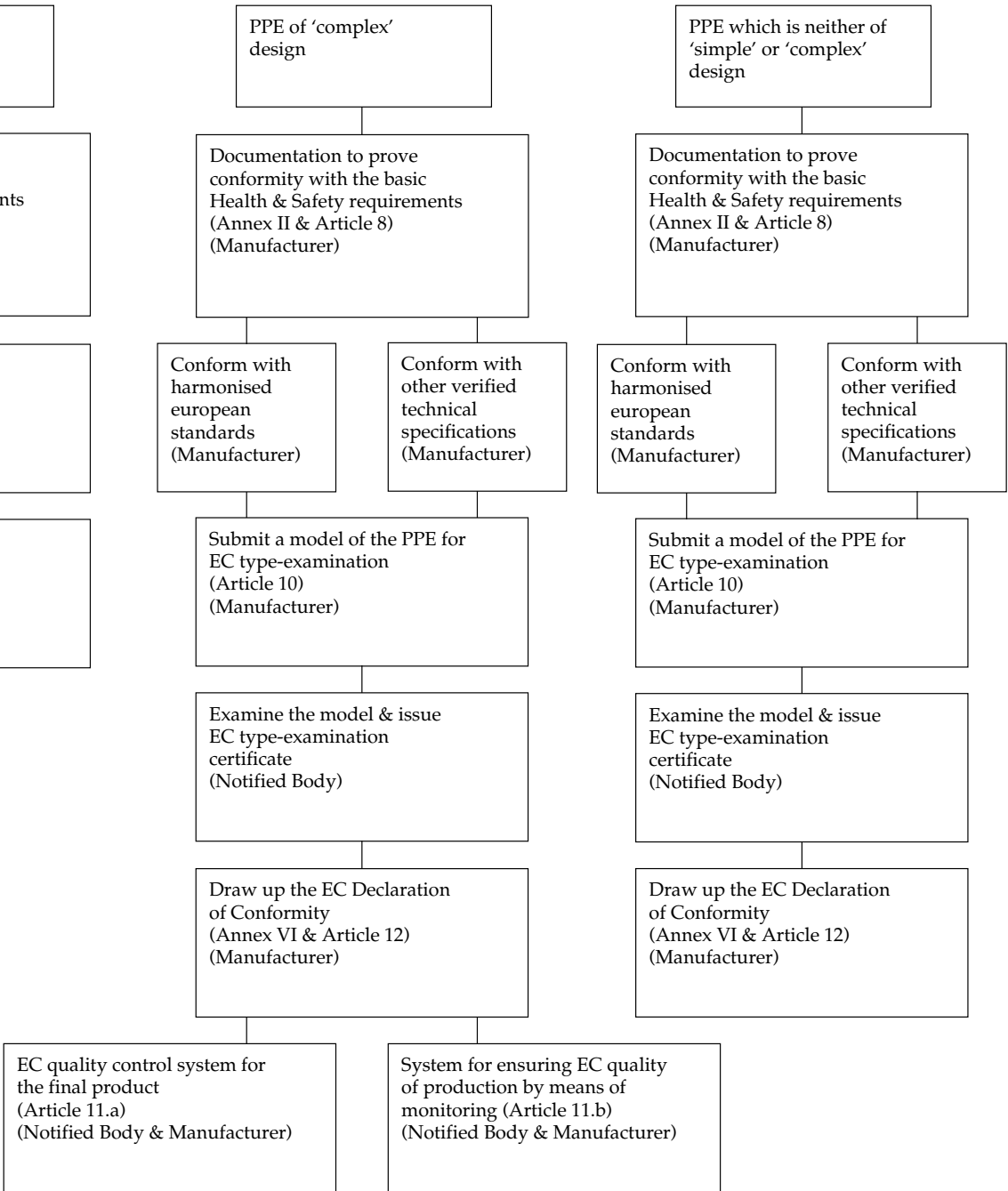


Figure 6
Personal Protective Equipment
Procedures for Attestation

- **Competent Body**

means any body which meets the criteria listed in Annex II of the Directive, has been Appointed by their National Authority and Notified to the European Commission.

2.5.3 Equipment Covered by the Directive

Annex III of the Directive gives an illustrative list of typical types of apparatus which electromagnetic disturbance should not affect such as audio and video equipment, manufacturing equipment, medical and scientific equipment, domestic appliances, lighting equipment and telecommunications networks and apparatus.

2.5.4 Exemptions

There are various exclusions to the Directive for example; amateur radio apparatus, Military equipment, apparatus wholly covered by other Directives, etc. [reference Article 2 of the Directive].

2.5.5 Directive Requirements

The Directive specifies the **protection requirements** for the construction of apparatus as:

- the electromagnetic disturbance it generates does not

exceed a level allowing radio and telecommunications equipment and other apparatus to operate as intended,

- the apparatus has an adequate level of intrinsic immunity to electromagnetic disturbance to enable it to operate as intended,

This is to ensure that the apparatus listed in Annex III of the Directive may continue to operate as intended when subject to the levels of disturbances in the harmonised standards.

2.5.6 Paths to Attestation

There are three routes by which a manufacturer, importer or authorised representative can demonstrate his apparatus complies with the Directive. These are shown in Figure 7.

(i) Standards Route

This route is used when the manufacturer designs and constructs his apparatus in conformance with an appropriate harmonised European Standard. No third party needs to be involved with this route although in practice many manufacturers use test reports from competent bodies to show compliance with the standards. Once satisfied that his apparatus complies with the EMC requirements, the manufacturer draws up and signs his Declaration of Conformity and affixes the CE Marking.

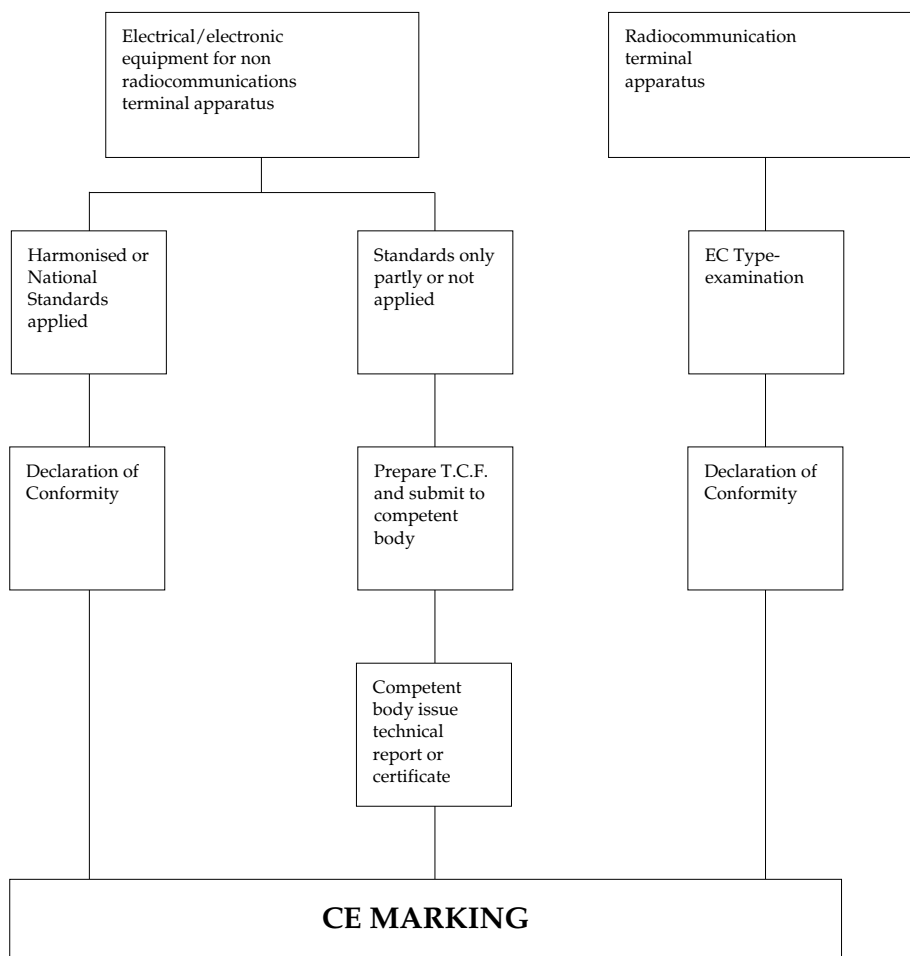


Figure 7
EMC Directive
Paths to Attestation

(ii) **Technical Construction File (TCF) Route**

This route is used where there are no harmonised or notified National standards available or where the manufacturer chooses to apply only part of the relevant standard. In this case, the manufacturer prepares a technical construction file for the apparatus.

This technical construction file is submitted to a Competent Body for assessment of the apparatus with respect to the requirements of the Directive who will issue a certificate or report stating the reasons for accepting or rejecting the apparatus.

Once the manufacturer is satisfied that his TCF and apparatus complies with the Directive, he affixes the CE Marking.

(iii) **EC Type-examination Route**

This route is for radiocommunication transmitting apparatus including mobile telephones. The manufacturer submits his apparatus to a Notified Body for examination and testing. On satisfactory completion, the Notified Body will issue an EC type examination certificate.

2.5.7 CE Marking

Until 1 January 1997, the manufacturer has the choice of two forms of the mark which may be used. The original as given in Directive 89/336/EEC [Annex I] or the amended version given in Directive 93/68/EEC [Article 5, Para 6]. From 1 January 1997, only that given in Directive 93/68/EEC can be used.

2.6 Low Voltage Directive (LVD).

2.6.1 General

The Low Voltage Directive (LVD), 73/23/EEC as amended by 93/68/EEC (Article 13) was established as an "Old Approach" Directive laying down the safety objectives, accepted by all Member States, to allow the free movement of electrical equipment within certain voltages throughout the European Union.

The LVD came into force on 19 August 1974 and was transposed into UK Law by Statutory Instruments (SI) 1989 No. 728 and SI 1994 No. 3260.

The amending Directive 93/68/EEC transposed the LVD into a "New Approach" Directive by requiring:

- a Technical Construction File (TCF),
- internal production control system to ensure the electrical equipment is manufactured in compliance with the requirements of the LVD,
- EC Declaration of Conformity,
- CE Marking of electrical equipment before being placed on the market,
- retention of the TCF for 10 years, (Note: must be kept on Community Territory).

This amending Directive came into force on 1 January 1995 and the CE Marking requirements do not become mandatory until 1 January 1997. Until 1997, manufacturers have the option of complying with the requirements of the original Directive or the amending Directive.

2.6.2 Definition

For the purpose of the LVD, electrical equipment means any equipment designed for use with a voltage rating of between 50 and 1000 volts for alternating current (a.c.) and between 75 and 1500 volts for direct current (d.c.).

2.6.3 Exemptions

The following list of equipment and phenomena are exempt from complying with the Directive:

- electrical equipment for use in an explosive atmosphere,
- electrical equipment for radiology and medical purposes,
- electrical parts for goods and passenger lifts,
- electricity meters,
- plugs and socket outlets for domestic use,
- electric fence controllers,
- radio-electrical interference,
- specialised electrical equipment, for use on ships, aircraft or railways, which complies with the safety provisions drawn up by international bodies in which the Member States participate,
- electrical equipment intended for export to countries outside the European Union.

2.6.4 Directive Requirements

These are termed the SAFETY OBJECTIVES. They are primarily to ensure that the electrical equipment is constructed in accordance with good engineering practice with regard to safety and that the equipment does not endanger the safety of persons, domestic animals or property when properly installed, maintained and used as intended.

These safety provisions are contained in harmonised European Standards. In the absence of harmonised standards, then the International Commission's Rules for the Approval of Electrical Equipment (CEE) and the International Electrotechnical Commission (IEC) standards, may be used, where they cover the safety provisions of the LVD.

2.6.5 Technical Construction File (TCF)

The TCF must be available for presentation to a Competent Authority on request. It should contain sufficient information for the electrical equipment to be assessed for compliance with the LVD. It must address the design, manufacture and operation of the electrical equipment and contain:

- a general description of the electrical equipment,
- design and manufacturing drawings with schemes of components, sub-assemblies, circuits, etc. as necessary,
- descriptions to allow the operation and drawings, etc. to be understood,
- list of standards applied or solutions adopted to satisfy the safety aspects,
- design calculations, examinations and test reports.

2.6.6 Production Control System

The manufacturer should have a quality control system for the production of his electrical equipment. The control system should ensure that each manufactured product is in conformity with the requirements of the Directive. The quality control system can be his own internal one and does not require to be approved by a third party.

2.6.7 EC Declaration of Conformity

When the manufacturer is satisfied his equipment complies with the LVD, he prepares his Declaration of Conformity, signs it (it must be kept with the TCF) and affixes the CE Marking. The Declaration must contain the following information:

- name and address of the manufacturer or his Community representative,

- a description of the electrical equipment,
- details of harmonised standards or specifications used,
- identification of the signatory empowered to sign the Declaration,
- last two digits of the year in which the CE marking was affixed.

2.6.8 CE Marking

The details of the CE marking are as shown in Figure 2. It may be affixed to the electrical equipment, the packaging, the introduction sheet or the guarantee certificate and must be visible, easily legible and indelible.

2.7 Overlap Between The Low Voltage (LVD) & Machinery Directives (MD).

Many Directives overlap with each other which causes a lot of confusion. This is particularly true for the Machinery and Low Voltage (LVD) Directives.

The Machinery Directive, Article 1.5 states, “Where, for machinery, the risks are mainly of electrical origin, such machinery shall be covered exclusively by Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws on the Member States relating to electrical equipment designed for use within certain voltage limits.”

The intended effect of this statement is far from clear especially as it is all but impossible in many cases to justify the choice of a “main” hazard. A Council Minute accompanying the Machinery Directive agrees that for electrical equipment already enjoying free arbitration under the terms of the LVD must not be effected by the MD. In practice of course both Directives have the same technical requirement – items must be adequately safe in respect of all hazards.

With the advent of CE Marking Directive the administrative requirements in respect of machinery, certification and the complying of a technical file are also the same for both Directives. As a result it can be argued that in complying with one Directive there is compliance with both. So the question of which is the main hazard can be successfully side-stepped. Both Directives are complied.

In addition CEN and CENELEC have developed a mutual common approach to the addressing of all hazards. As a consequence a standard harmonised for the MD is also harmonised for the LVD.

3. TYPICAL EC TYPE EXAMINATION OF AN ANNEX IV MACHINE UNDER THE MACHINERY DIRECTIVE

This section will consider a typical EC Type Examination procedure as it would be carried out by Lloyd’s Register for an Annex IV machine to the Machinery Directive, as amended.

This same basic procedure may be used as a guide for undertaking an EC Type Examination for other Directives, provided, where necessary, the specific requirements of that Directive are applied.

Equally, this procedure may be used by manufacturers when demonstrating compliance to a Directive under a self certification module. In such cases, the review and testing requirements are carried out by appointed member(s) of the firm instead of the Notified Body.

3.1 Background to Type Examination

The Machinery Directive and its amendments appear complicated on a first review, with its many onerous safety aspects [the **Essential Safety Requirements (ESR’s)**]. However, in view of the range and combination of machinery covered, this is a natural reaction. Where hazards are found to exist for a specific machine, then action must be taken to remove, minimise or warn against them, in that order of importance. This may be by design, providing safeguards or by a warning sign. Essentially, the ESR’s are a compilation of the safety features which have been required by the Member States’ legislation or good engineering practice for a number of years. The majority of manufacturers have been complying with these for many years and therefore they should not present a problem. It is the associated paperwork which may present a problem, as it is required to contain specific information which may not have been previously provided. Once standards are available for the various machinery, manufacturers will have additional choices by which to demonstrate compliance with the Directive. They will also alleviate many of the interpretation difficulties currently being experienced by providing guidance on the current state of the art and philosophy on meeting the essential requirements. Though the use of harmonised standards is not mandatory, using them to demonstrate compliance gives a presumption of conformity with the ESR’s of the Directive which they cover. Until **harmonised standards** are available, manufacturers can resort to the use of guidance notes and existing standards prepared by Manufacturers’ Associations and Government Standards Bodies for demonstrating compliance with the ESR’s. In many cases, they also give valuable guidance on methods by which the hazards identified through the **Risk Assessment** may be eliminated.

Firstly to recap the attestation paths available for demonstrating compliance of **Annex IV** machinery before affixing the CE Marking:

- i) Where the machinery is manufactured in compliance with the **specific Harmonised Standard**, the manufacturer may submit his **Technical Construction File (TCF)** to a **Notified Body (NB)** and request them to;
 - a) acknowledge receipt and retain it,
or
 - b) review it for correct application of the standards and issue a **Certificate of Adequacy**,
or
 - c) submit the machinery for an **EC Type Examination**.

Note:

The choice of (a), (b) or (c) is made by the manufacturer.

- ii) Where the Harmonised Standards are not complied with or only partially complied with or where no Harmonised Standard exists, then the machinery must be presented to a NB for an **EC Type Examination**.

3.2 EC Type Examination

The basic procedures for carrying out a typical EC Type Examination may be considered under the following headings:

Enquiry

Risk Analysis

Documentation Preparation

Documentation Review

Inspection and Testing

Certification

Signing of Declaration and Affixing CE Marking

3.2.1 Enquiry

This is a very important part of the process. The manufacturer discusses with his chosen Notified Body the most advantageous procedure to allow the approval to progress smoothly through each stage. Misunderstandings and procedures are discussed to alleviate the possibility of problems occurring at crucial stages.

Typical topics discussed at this time are:

- **Attestation modules**

The available modules for the machinery under review and which would be the most suitable is discussed. Once this is agreed, the manufacturer can then plan according to his market commitments, time and cost constraints.

- **Technical construction file (TCF)**

The contents of the TCF are discussed to ensure that only the pertinent information is included. It should be limited to that which will allow a third party to review quickly and thoroughly the data to confirm the machinery satisfies the requirements of the Directive.

The range of machines for approval will also be considered. In many cases one TCF is sufficient to cover the range with any differences being covered in an Appendix.

- **Brochures**

The inclusion of brochures can be an excellent source of information in a TCF especially those which contain detailed information and photographs of the machinery. It is appreciated that sometimes other machines are featured in these and in such cases, the manufacturer should clearly identify those pages and items which are relevant to the machinery under approval.

- **Drawings**

The drawings required depend on the complexity of the machinery. General arrangement drawings of the machine, electrical system, hydraulic or pneumatic system and control systems are required giving details of dimensions, materials and power supplies as required. Drawings of components and circuits which demonstrate

a control or safety feature, or give a better understanding of the operational function are included, where necessary. Detailed manufacturing drawings are not required.

- **Instruction manual**

In their current form, these do not always contain all the information required by the Directive. Where the omissions are minor, they may be covered by a supplement which can be included at the next scheduled printing. Typical omissions are: airborne noise emissions, installation and assembly instructions to reduce noise or vibration, warnings on ways in which the machinery should not be used, etc.

- **Inspection and testing**

This would cover the typical tests required and the location at which these may be undertaken. This allows the Client to make advance preparations for sampling and testing. The local LR surveyor's involvement regarding the selection of samples, inspection and testing would also be discussed.

- **Fees**

Information would be gathered to allow a fee quotation to be prepared. This would cover the types, number of machines and location of testing,

- **Time scales**

These would be discussed and assessed in relation to the average times anticipated for each part of the approval taking into account the requirements of the manufacturer and the Notified Body. This gives both parties some idea of the timescale to which they must schedule their work.

The following documents have been prepared to assist with these discussions between the manufacturer and Lloyd's Register (LR):

- **LR PRODUCT CERTIFICATION SYSTEM PROCEDURE PC93**
- **GUIDANCE NOTES FOR THE MACHINERY DIRECTIVE**
- **REQUEST FOR LR PRODUCT CERTIFICATION TO EC DIRECTIVES**

The **Procedure PC93** gives information on the procedures LR applies in dealing with Product Certification to the Directives and are uniformly applied by LR worldwide. They cover topics governing the application, the information to be submitted for review, the inspection and testing requirements and the issue and control of certificates.

The **Guidance Notes** detail some of the more important issues contained in the Machinery Directive as amended. Details such as: Routes to Attestation, dates of implementation, CE Marking, etc.

The **Request Form**, allows the Client's data and the pertinent information relating to the approval to be recorded. A completed request form is required for all work undertaken by LR.

3.2.2 Risk Assessment

A risk analysis is a process whereby the hazards presented by the machinery at various stages (e.g. the design, manufacture, operation, maintenance, etc.) are assessed and documented to allow corrective action to be taken to eliminate or minimise these hazards and produce an acceptably safe machine. Annex I

of the Machinery Directive lists the essential requirements which the machinery must satisfy. It is the responsibility of the manufacturer to identify those hazards presented by his machine and taking into consideration the state of the art, take all reasonable precautions to eliminate or minimise them.

A risk assessment would normally cover the following points for the hazards given in Figure 8 and may be laid out as shown in Figure 9.

- the hazardous situations and events that can cause harm,
- the foreseeable probability and severity of harm which could result,
- the complexity of the machine as far as safety is concerned,
- the human interaction with the machine during all operations including foreseeable misuse,
- the intended use of the machine,
- the limitations of the machine,
- materials etc., to be processed,
- requirements for installation, commissioning, maintenance, cleaning etc.,
- machinery safety features,
- accident history, (where available),
- experience required by personnel to operate the machinery.

From the risk assessment, the manufacturer identifies the ESR's to be complied with and decides on the corrective action to satisfy the requirements of the Directive. This process also assists with the identification of the documentation required to be included in the TCF. Guidance on risk assessment may be obtained from the following harmonised standards: EN 292, EN 414, prEN 1050.

3.2.3 Documentation

Having carried out the risk assessment, listed and stated how each ESR is satisfied, the documentation for the Technical Construction File is assembled.

Machinery which has been in production for some time and been successfully sold in the market place for several years, prior to the Directive becoming mandatory, may prove a problem with compliance with the Directive. Except, where the manufacturer took into account the latest guidance notes prepared by the various Manufacturing Associations and Government Bodies during its design. For the majority of manufacturers, it will be the assembling of the documentation which may cause a few problems in the early stages. This is primarily due to the way the information is required to be presented rather than it not being available.

Mechanical	<ul style="list-style-type: none"> • crushing • shearing, • cutting or severing, • entanglement, • trapping or drawing-in, • impact, • stabbing or puncture, • friction or abrasion, • high pressure fluid,
Thermal	<ul style="list-style-type: none"> • burns and scalds • hot or cold environment
Vibration	<ul style="list-style-type: none"> • transmitted to body or hands and arms
Radiation	<ul style="list-style-type: none"> • radio frequency and micro-waves • infra-red • visible light • ultra-violet • X and γ rays • α, β rays, electron or ion beams • neutrons
Electrical	<ul style="list-style-type: none"> • contact with live parts, • approach to high voltage live parts • unsuitable or poor insulation • electrostatic • thermal radiation i.e. molten particles, chemical effects from short-circuits, overloads
Noise	<ul style="list-style-type: none"> • permanent loss of hearing acuteness • tinnitus • tiredness, stress etc. • effects such as loss of balance, awareness etc. • interference with speech communication, • acoustic signals etc.
Ergonomic	<ul style="list-style-type: none"> • physiological effects • Psycho-physiological effects • human errors
Materials and substances	<ul style="list-style-type: none"> • contact with or inhalation of fluids, gases, mists, fumes, dusts, having toxic, corrosive and/or irritant effect. • fire and explosion • biological and micro-biological.

Figure 8
Hazards Generated by Machinery

Figure 9 Risk Assessments – Example of Mechanical Hazards

Hazard	Mechanism	Severity	Occurrence	Circumstances when Hazard occurs	Method of reducing Hazard
Crushing	Cams and linkages Knives Ram Drive sprockets	Disabling Disabling Disabling Disabling	Possible Likely Disabling Possible	Normal use Servicing Cleaning Maintenance	Fixed and interlocked moveable guards Hopper mouth 1000mm from danger zone Hopper mouth 1000mm from danger zone Fixed guards
Shearing	Dams and linkages Knives Ram Drive sprockets	Disabling Disabling Disabling Disabling	Possible Possible Possible Possible		Fixed and interlocked moveable guards Hopper mouth 1000mm from danger zone Hopper mouth 1000mm from danger zone Fixed guards
Cutting	Knife Sheet metal edges	Disabling Low	Probable Probable	Normal use Servicing Cleaning Maintenance	Hopper mouth 1000mm from danger zone Edges smooth during manufacture
Entanglement	Cams and linkages Drives and sprockets Drive belts	Moderate Moderate Moderate	Possible Possible Possible		Fixed and interlocked moveable guards Fixed guards Fixed and interlocked moveable guards
Drawing-in or trapping	Drive sprockets Drive belts Conveyor belt	Moderate Moderate Low	Possible Possible Probable		Fixed guards Fixed and interlocked moveable guards Drive roller spring loaded

Let us now consider the contents of a typical TCF. This is not a definitive list but an illustration of the typical information required to be included in a TCF. In general, a TCF should contain the minimum amount of information which will allow a third party to assess the machine's compliance with the requirements of the Directive.

- **Technical Construction File Contents**

- General drawings of the machinery showing its construction, power supplies, location of the guarding and safety arrangements with pertinent dimensions and material details.
- Description of the machinery, its operation and the control systems supplemented with circuit diagrams for the electrical, hydraulic and pneumatic systems as necessary.
- Description with drawings, where necessary, of the safety arrangements and their functions.
- Any calculation notes, test results, etc., previously carried out, which were used in the design or to check conformity.
- List of the applicable ESR's, with a description of how these are complied with.
- List of the applied standards or specifications used in the design of the machinery. These may be incorporated in the descriptive list of compliance with the ESR's.
- Details of the manufacturer's markings on the machine.
- Instruction manual, (the following may be required to be dealt with, transportation, installation, commissioning, cleaning, overhaul, maintenance, decommissioning, disposal and spares).
- Proposed Test schedule.

- **Instruction Manual**

There are specific requirements to be included in the Instruction Manual which are to be found in Annex I, para 1.7.4 of the Directive.

The following give some guidance on information which should be included:

- name and address of supplier,
- details of authorised service and repair agencies,

- description of the machinery with pertinent data,
- information of the markings on the machinery:
 - name and address of manufacturer,
 - CE Marking,
 - designation of series or type,
 - serial number, if any,
 - year of construction, etc.
- installation process including requirements for foundations, power supplies, services, ambient conditions, minimising noise and vibration, workstations, etc.,
- assembly and dismantling,
- commissioning procedures,
- operating instructions,
- control systems including circuit diagrams for electrical, hydraulic and pneumatic systems,
- adjustment procedures including details of any tests which are required after adjustment,
- tools which can be used with the machine, how fitted and set,
- maintenance requirements (servicing, cleaning and repair) including details of any test requirements on completion. Periodic examination and/or maintenance should be possible with equipment or tools generally available or such tools or equipment should be provided with the machinery,
- specification for any fluid to be used in hydraulic systems and for lubrication, braking or transmission systems,
- details of spares and their fitting,
- precautions including warnings of dangers and known areas of misuse,
- any necessary drawings to illustrate the foregoing,
- vibration levels ,
- noise emission information. The condition of the machinery when the noise levels were measured must be stated. (These may be measured in accordance with ISO/DIS 8500 and ISO/DIS/230 in the absence of other suitable standards.),
- information where the machinery can be used in potentially explosive atmospheres,
- When the machinery may be used by a non-professional person, the instructions should take this into consideration.

This TCF is now submitted for review.

Note:

The Instruction Manual must be drawn up in one of the Community languages acceptable to Lloyd's Register. When the machinery is put into service, the Instruction Manual must be in the language of the country to which it is being supplied and accompanied with a copy in the original language. Where the maintenance is only to be carried out by specialist personnel employed by the manufacturer then the maintenance instructions may be in one Community language which is understood by them.

- **Review of Documentation**

On receipt of the documentation, it is allocated to an Engineer authorised to conduct reviews for Annex IV machinery of the type involved. During the review of the TCF the following points are considered:

- contents, to ensure all the requirements have been covered,
- all applicable ESR's have been taken into consideration,
- methods applied for compliance with the ESR's satisfy the requirements,
- instructions are clear and do not contradict any of the ESR's,
- standards have been correctly applied,
- required data and markings are given and are correct,
- necessary tests to demonstrate conformity, if not already carried out and supported with acceptable test reports, are included in the test programme,

Any discrepancies found during the review, are advised to the client to allow him to take the necessary corrective action. The amendments are reviewed for confirmation.

- **Inspection and Testing**

On completion of the documentation review, during which the inspection and testing requirements have been discussed and agreed with the manufacturer, arrangements will be made to witness these in accordance with the test schedule. These inspection and tests will be carried out by the local LR office at the manufacturer's works or test laboratory as agreed.

The following illustrates a typical test schedule:

1. **Visual and dimensional inspection**

To confirm that the machinery is constructed as per the drawings, that the clearances and openings are as stated on the drawings and in the TCF and that the requirements of the applied standards, etc. are satisfied.

2. **Check of alarms, interlocks, safety functions, safeguards, visual and audible warnings**

Verify functionality of each alarm and safety feature in terms of operation, visual and audible signals and that it will alert the operator or other personnel in the vicinity to a possible dangerous situation.

3. **Operational test covering each mode of operation**

The machinery is operated in and from each control position in turn to confirm that the safety feature functions are satisfactory and provide the necessary protection to the operator(s) and other personnel in the vicinity.

4. **Check of Emergency Stop and speed of response**

Check the emergency stop function. Where several command stations may be selected, confirm that the emergency stop cannot be isolated with the command stations. It must also be able to bring the machinery to a safe condition within the required period of time. After activation and correction of the fault, the machinery must only start by a positive command from the operator.

5. **Check system restart after shutdown command**

Check that after a shutdown command, facilities are provided to allow the tool position etc. to be adjusted to a safe position, when required, before any investigation is carried out. Also, that the machine will only restart by a command from the operator once it is safe to do so.

6. **Check of hydraulic and pneumatic system safety devices**

Check their relief arrangement settings, safety interlock functions, securing, containment and protection arrangements.

7. **Check safe distance provisions**

Check that the safeguards prevent the operator and/or other personnel in the vicinity from entering a dangerous area while the machine is operating.

8. **Electrical tests**

General inspection and tests as per EN 60204, for example:

- continuity of the protective bonding circuit,
- insulation resistance tests,
- voltage tests,
- protection against residual voltages,
- electromagnetic tests,
- functional tests,

9. **Check operation of any optional equipment which may be fitted**

Check any optional equipment which can be fitted to the machinery to ensure it does not affect the machine's safety.

10. **Check markings**

Check the markings on the machine to ensure they are correct and comply with the information given in the TCF.

On completion, a test report is drawn up and signed by the witnessing representatives of the manufacturer and Lloyd's Register confirming the accuracy of the contents. This is submitted to the reviewing office for verification with the requirements.

- **Certification**

On satisfactory review of the test report and if all other requirements have been met, an EC Type Examination Certificate is prepared and signed by the authorised engineer. This certificate contains the information required by the Directive and is forwarded to the client to add to and complete his TCF.

The documentation and certification reviewed in the process of issuing an EC Type Examination Certificate is retained by Lloyd's Register for the statutory period in compliance with UK National Law.

- **Signing of Declaration and Affixing CE Marking**

Having received the EC Type Examination Certificate, the client may now prepare his **DECLARATION of CONFORMITY**. The contents to be included in the Declaration are found in Annex II of the Directive. Once the manufacturer or his representative is satisfied that his machinery satisfies the requirements of the Directive(s) applicable to it, the Declaration is signed and the **CE Marking** affixed.

A sample format for a Declaration of Conformity is shown in Figure 10.

For **Safety Components** which have been Type Examined in compliance with the Directive a **Declaration of Conformity** is prepared but the **CE Marking** is **NOT** affixed. The CE Marking on the machine, after incorporation, covers these components.

Note:

The **CE Marking** is not affixed to machinery covered by a **Declaration of Incorporation**. A sample format is shown in Figure 11.

turer should bear in mind that if the TCF is not produced within a reasonable time period, it could be interpreted that he failed to carry out his obligations under the Directive.

3.3 Modifications to Annex IV Machinery

Where modifications are to be made to machinery which is covered by an EC Type Examination, then the manufacturer or the responsible person must advise the Notified Body of the proposed changes. Even minor changes must be advised. On receipt, the Notified Body will review the modification details and advise if the certificate remains valid or if additional testing is required. The manufacturer may then take corrective action to allow either an amended or a new certificate to be issued.

3.4 Conclusion

This section of the paper has aimed at clarifying the process of carrying out an EC Type Examination and may be useful as a future reference document. This has been done by:

- demonstrating that the process of attestation to the Machinery Directive is generally a drawing together of current practice in the industry,
- giving guidance on the contents expected in the documentation and that it should be presented in a prescribed manner and,
- helping with the understanding of the procedure to be followed to meet the requirements of the Directive.

Co-operation and dialogue between the manufacturer and LR is important for machinery listed under Annex IV of the Directive. It assists in streamlining the procedure, minimising problems and minimising the time taken for the approval process.

Note:

For manufacturers whose machinery is not listed under Annex IV, the route is similar to that described above with the following exceptions:

- The services of a Notified Body are not necessary. However, if a manufacturer wishes, he may use their services or those of another suitable competent Third Party.
- Though they do not physically have to assemble the TCF, they must have identified its contents and be able to produce it when requested, by a competent National Authority i.e. in the event of an accident. The manufac-

EC DECLARATION OF CONFORMITY

We hereby declare that the following machinery complies with the essential health and safety requirements of the Machinery Directive 89/392/EEC, 91/368/EEC and 93/44/EEC.

Machine description:.....

Make:..... Type:.....

Serial Number:.....

Manufactured by:.....

Address:.....

.....

.....

.....

This machinery has been designed and manufactured in accordance with the following transposed harmonised European standards:

EN292 parts 1 and 2: 1991 Safety and Machinery - Basic concepts, general principles for design.

EN294: 1992, Safety of Machinery - Safety distances to prevent danger zones being reached by the upper limbs.

EN349: 1993, Safety of Machinery - Minimum gaps to avoid crushing of parts of the human body.

EN418: 1992, Safety of Machinery - Emergency stop equipment, functional aspects - Principles for design.

EN60204 part 1: 1993, Safety of Machinery - Electrical equipment of machines - Specification for general requirements.

.....

.....

.....

and to the following British Standards:

British Standard BS5304: 1988, Safety of Machinery

EC Type Examination is covered by Certificate No.:.....

Issued by:.....

Address:.....

.....

.....

.....

A technical construction file for this machinery is retained at the following address:

.....

.....

.....

Signed:..... Date:.....

Name:..... Position:.....

Address:.....

.....

.....

.....

Appointed by the manufacturer as the responsible person for signing this Declaration.

Figure 10
EC Declaration of Conformity

EC DECLARATION OF INCORPORATION

We hereby declare that the following machinery is intended to be incorporated into other machinery and must not be put into service until the machinery into which it is incorporated has been declared in conformity with the essential health and safety requirements of the Machinery Directive 89/392/EEC, 91/368/EEC and 93/44/EEC and CE Marked.

Machine description:

Make: Type:

Serial Number:

Manufactured by:

Address:

.....

.....

.....

This machinery has been designed and manufactured in accordance with the following transposed harmonised European standards:

EN292 parts 1 and 2: 1991 Safety and Machinery - Basic concepts, general principles for design.

EN294: 1992, Safety of Machinery - Safety distances to prevent danger zones being reached by the upper limbs.

EN349: 1993, Safety of Machinery - Minimum gaps to avoid crushing of parts of the human body.

EN418: 1992, Safety of Machinery - Emergency stop equipment, functional aspects - Principles for design.

EN60204 part 1: 1993, Safety of Machinery - Electrical equipment of machines - Specification for general requirements.

.....

.....

.....

and to the following British Standards:

British Standard BS5304: 1988, Safety of Machinery

EC Type Examination is covered by Certificate No.:

Issued by:

Address:

.....

.....

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A technical construction file for this machinery is retained at the following address:

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.....

.....

Signed: Date:

Name: Position:

Address:

.....

.....

.....

Appointed by the manufacturer as the responsible person for signing this Declaration.

Figure 11

4 CONCLUDING REMARKS

- 4.1 Directives will have an increasing impact on trade within the European Union (EU). In consequence they will have, and continue to have, a major effect on LR's business in both traditional and non-traditional areas of work worldwide. Directives requiring the CE marking of equipment offered for sale within the EU will in many instances require the services of a body such as LR.
- 4.2 Bearing this in mind this paper has been prepared to provide surveyors with sufficient understanding of the principles and application of Directives to allow informed discussions with prospective clients. Because of the volume and variety of the subject it has been difficult to select suitable topics to keep the paper within manageable proportion whilst maintaining its usefulness. As a consequence the paper is not intended to replace the various Directives, but to be an aid to deciphering and understanding their language, form and contents.
- 4.3 Further, it must always be remembered that Directives are the method by which the EU Member States unify their different legal requirements in order to remove existing barriers to trade. The process of obtaining this unification is laborious, and often results in confusing requirements as each Member State tries to incorporate its own current laws. In spite of this, Directives in general are effective, though the playing fields are as yet by no means level. However leveling will eventually come as implementation and interpretation becomes more standardised throughout the Member States.
- 4.4 At long last Directive formats are beginning to follow a standard pattern. e.g. The paths of attestation are following the Council Decision (90/683/EEC) "concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonisation directives". This increased standardisation will help with the understanding of the requirements of future directives.

5. ACKNOWLEDGMENTS

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6. BIBLIOGRAPHY

- 6.1 Council Decision 90/683/EEC concerning the modules for the various phases of conformity assessment procedures which are intended to be used in the technical harmonization directives. O.J. No 380, 31.12.90, p13
- 6.2 Council Directive 93/68/EEC amending Directives 87/404/EEC (simple pressure vessels), 88/387/EEC (safety of toys), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC (personal protective equipment), 90/384/EEC (non-automatic weighing instruments), 90/385/EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits). O.J. No L 220, 30.8.93, p1
- 6.3 Machinery (MD)
- Council Directive 89/392/EEC on the approximation of the laws of the Member States relating to machinery. O.J. No L 183, 29.6.89, p9
 - Council Directive 91/368/EEC amending Directive 89/392/EEC on the approximation of the laws of the Member States relating to machinery. O.J. No L198, 22.7.91, p16
 - Council Directive 93/44/EEC amending Directive 89/392/EEC on the approximation of the laws of the Member States relating to machinery. O.J. No L 175, 19.7.93, p12
- 6.4 Simple pressure Vessels (SPV)
- Council Directive 87/404/EEC on the harmonisation of the laws of the Member States relating to simple pressure vessels. O.J. No L 220, 8.8.87, p48
 - Council Directive 90/488/EEC amending Directive 87/404/EEC on the harmonisation of the laws of the Member States relating to simple pressure vessels. O.J. No L 270, 2.10.90, p25
- 6.5 Recreational Craft (RCD)
- Directive 94/25/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft. O.J. No L 164, 30.6.94, p15
- 6.6 Personal Protective Equipment (PPE)
- Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment. O.J. No L 399, 30.12.89, p18
 - Council Directive 93/95/EEC amending Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment. O.J. No L 276, 9.11.93, p11
- 6.7 Electromagnetic Compatibility (EMC)
- Council Directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility. O.J. No L 139, 23.5.89, p19
- Council Directive 92/31/EEC amending Directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility. O.J. No L 126, 12.5.92, p11
- 6.8 Low Voltage (LVD)
- Council Directive 73/23/EEC on the harmonization of the laws of the Member States relating to electrical equipment designed for the use within certain voltage limits. O.J. No L 77, 26.3.73, p29

7 GLOSSARY

CEN	European Committee for Standardization.
CENELEC	European Committee for Electrotechnical Standardization.
ETSI	European Telecommunications Standards Institute
EN	European Standard
HD	Harmonization Document
ENV	European Prestandard
prEN	draft European Standard
prHD	draft Harmonization Document.
prENV	draft European Prestandard
NB	Notified Body
A.I.B.	Authorised Inspection Body
Harmonized Standards	a technical specification adopted by a European Standards organization to satisfy the requirements of a directive and which is published in the O.J.
O.J.	Official Journal of the European Community
Attestation	approval route by which compliance with a directive may be demonstrated.
Authorised Inspection Body	a third party authorized to perform the conformity assessment tasks specified in the Simple Pressure Directive, which has been appointed by a Member State from the bodies falling within its jurisdiction, which has the necessary qualifications, meets the requirements laid down in the directive and has been notified to the Commission and to the other Member States
Notified Body	a third party authorized to perform the conformity assessment tasks specified in the directive, which has been appointed by a Member State from the bodies falling within its jurisdiction, which has the necessary qualifications, meets the requirements laid down in the directive and has been notified to the Commission and to the other Member States
Competent Body	a third party authorized to perform the conformity assessment tasks specified in the Electromagnetic Compatibility Directive, which has been appointed by a Member State from the bodies falling within its jurisdiction, which has the necessary qualifications, meets the requirements laid down in the directive and has been notified to the Commission and to the other Member States
Hazard	is a source with the potential to cause harm
Risk	is the possibility of an undesired event occurring due to the realization of a hazard.
Risk assessment	is a qualitative or quantitative evaluation of the chance that a hazard will cause harm, which identifies and takes account of all the significant factors that can affect the chance and extent of harm, and which reaches a conclusion on whether and how management of such factors needs to be improved,

to eliminate or lessen that chance.

Directives	agreed safety requirements accepted by all Member States which must be transposed into their National Law giving one universal set of European requirements.
Statutory Instruments	these are UK National regulations which transpose the European Directives into UK Law. Other Member States have equivalent regulations.
European Union Member States	Belgium; Denmark; France; Germany; Greece; Ireland; Italy; Luxembourg; Netherlands; Portugal; Spain; UK; Austria; Finland and Sweden
EFTA Member States	(European Free Trade Association) Norway; Liechtenstein; Iceland and Switzerland
Competent Authority	a body appointed by the Member State to monitor, in that state, compliance of products with a Directive.
CE Marking:	is a logo affixed by a manufacturer to show that his product is in conformity with the requirements of a Directive. Note: it is not a quality mark.
Authorized Representative	a person established in the European Union who is appointed by a manufacturer to act on his behalf in carrying out certain duties required by the Directive.
Putting into Service	first used within the Community by the end user of a product covered by a directive.
Placing on the Market	the initial action of making available on the Community market, for payment or free of charge, a product covered by the Directive, with a view to distribute and/or use in the Community.
Transitional Period	the [period between the date on which a directive enters into force and the mandatory date during which either the national law implementing the Community directive or the previous national law may be applied.
Presumption of Conformity:	products which meet national standards that have transposed harmonized standards whose title has been published in the O.J. confers a presumption that the essential requirements covered by the standards are satisfied.
Technical Documentation	a file containing certain technical information which demonstrates the conformity of the product with the essential requirements of the directive.